Certificate of Analysis

Product name: **Atropini sulfas**

Batch number / Weight: **23J24-B05-233657 / 1 G**

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23J24-B05 / INS-23-8492**

Reference Code / No.: **V00776 / A-APS2206002**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) White, crystalline powder or colorlesscrystals	Conform		
Identification A	-0,50 - +0,05	-0,012	°	
Identification B	Conform	Conform		
Identification E	Conform	Conform		
pH	4,5 - 6,2	5,21		
Optical rotation	-0,50 - +0,05	-0,012	°	
Related substances	Conform	Conform		
Impurity A	<=0,2	0,05	%	
Impurity B	<=0,2	0,00	%	
Impurity C	<=0,2	0,00	%	
Impurity D	<=0,2	0,00	%	
Impurity E	<=0,3	0,00	%	
Impurity F	<=0,2	0,00	%	
Impurity G	<=0,2	0,00	%	
Impurity H	<=0,3	0,00	%	
Unspecified impurities	<=0,10	0,048	%	
Total impurities	<=0,5	0,15	%	
Water (Karl Fischer)	2,0 - 4,0	3,02	%	
Sulphated ash	<=0,1	0,00	%	
Assay Atropine sulphate	99,0 - 101,0	99,78	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:
Dominika Sołtysik
Qualified Person

07-12-2023

Expiration: 20-06-2025

Conclusion: APPROVED

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